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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON DC 20004

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OFFICE OF PETITIONS

In re Patent No. 7,462,623 :
Ple :
Issue Date: December 9, 2008 :
Application No. 10/533,931 : DECISION ON REQUEST FOR
Filed: May 4, 2005 : RECONSIDERATION OF
Attorney Docket No. 056291-5205 : PATENT TERM ADJUSTMENT
Title: Quinazoline Derivatives :
as SRC Tyrosine Kinase :
Inhibitors :

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)and (d) For Failure to Add Further Patent Term Adjustment Under § 1.702(b)" filed February 9, 2009. This petition is properly treated under 37 CFR § 1.705(d).

The application for reconsideration of patent term adjustment is **DISMISSED**.

The above-identified application matured into U.S. Patent No. 7,462,623 on December 9, 2008. The patent issued with a patent term adjustment of 551 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See, 37 CFR 1.705(d). Patentee requests that the patent term adjustment determination for the above-identified patent be changed from 551 days to 758 days.

Patentee requests recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to Wyeth, a PTO delay under 35 U.S.C. 154(b)(1)(A) overlaps with a delay under 35 U.S.C. 154(b)(1)(B) only if the delays occur on the same day.

The petition submitted by patentee sets forth a period of adjustment for Office delays totaling 772 days (Three Year Delay under 37 CFR 1.703(b) of 219 days *plus* a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a) of 553 days). The petition also sets forth an overlap of 12 days. The petition also reflects a reduction of patent term adjustment totaling 2 days for applicant's failure to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. Thus, patentees assert entitlement to an overall adjustment of 758 days (772 days (553+219) Office delay minus 12 days for overlap minus 2 days for applicant's delay).

Patentee's petition acknowledges the adjustments under 37 CFR 1.702(a) totaling 553 days. Patentee's petition also acknowledges the reduction for applicant's failure to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. This reduction totals 2 days.

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704.

The Office agrees that because certain actions were not taken within specified time frames, the patent is entitled to an adjustment of 553 days pursuant to 37 CFR 1.702(a). However, it should be noted that the calculation of any over three year delay for an application filed pursuant to 35 USC 371 is calculated based upon the commencement date. In this instance the commencement date of the application was May 4, 2005. Thus, the application was pending three years and 219 days until the issuance of the patent on December 9, 2008. For purposes of this decision the Office will utilize, patentees' calculations. As the Office contends the 219 days overlaps with the 553 days for examination delay.

At issue is whether patentees should accrue an additional 219 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 553 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 219 days overlap. Patentees' calculation of the period of overlap is inconsistent with the

Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

> To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

> To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

> If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See, 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See, Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See, also, Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final

> Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See, also, Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing or commencement date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

> Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a

> patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718[1]

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing or commencement date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, May 4, 2005, to the date the patent issued on December 9, 2008 (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)). Prior to the issuance of the patent, 553 days of patent term adjustment were accorded for the Office failing to respond within specified time frames during the pendency of the application. The 553 days accorded pursuant to 37 CFR 1.702(a) overlap with the 219 days of Office delay under 37 CFR 1.702(b).

The application actually issued three years and 219 days after its filing date. The Office did not delay 553 days and then delay an additional 219 days. Accordingly, 553 days of patent term adjustment (not 219 days and 553 days) was properly entered because the period of delay of 219 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 553 days attributable to grounds specified in § 1.702(a). Entry of both periods is not warranted. Thus, 553 days, which includes the 219 days pursuant to 37 CFR 1.702(a), is determined to be the actual number of days that the issuance of the patent was delayed.

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[1] The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

Accordingly, at issuance, the Office properly entered an overall adjustment of 553 days of patent term adjustment for the Office taking in excess of three years to issue the patent.

In view thereof, no adjustment to the patent term will be made because the correct adjustment of 551 days is properly set forth in the Letters Patent (adjustments totalling 553 days less reductions totalling 2 days).

The Office acknowledges submission of the required $200.00 application fee. See, 37 CFR 1.18(e).

Telephone inquiries specific to this matter should be directed to Petitions Attorney Charlema Grant, at (571) 272-3215.

Kery A Fries

Kery Fries
Senior Legal Advisor Attorney
Office of Patent Legal Administration